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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Boston Scientific Scimed (BSS) Atlantis™ PV Imaging Catheter

Submitted by: Boston Scientific Scimed
IVUS Technology Center
47900 Bayside Parkway
Fremont, CA 94538

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Date prepared: July 19, 2002

Proprietary Name: Atlantis™ PV Imaging Catheter

Common Name(s): Ultrasound Diagnostic Imaging Catheter
Diagnostic Ultrasound Transducer (90ITX)
Diagnostic Intravascular Catheter (74DQO)

Classification Name(s): Diagnostic Ultrasound Transducer,
21 CFR Part 892.1570 (90ITX); Diagnostic
Intravascular Catheter, 21 CFR Part 870.1200
(74DQO)

Predicate Device(s): The Atlantis™ PV Imaging catheter is
substantially equivalent to the following
devices:

Product	510(k)	Clearance Date
BSS Sonicath Ultra™ 6 (6F / 20 MHz)	K890772	May 10, 1989
BSS Sonicath Ultra™ 3.2 (3.2F / 20 MHz)	K970049	June 20, 1997

Description of the Device:

The Atlantis™ PV Imaging Catheter consists of two main assemblies:

- an over-the-wire (OTW) exchange style sheath assembly
- an imaging core assembly

The sheath is comprised of the following three sections:

- Radiopaque soft tip
- Proximal dual lumen
- Telescoping section

The radiopaque soft tip and proximal dual lumen sections comprise the “working length” of the catheter, and the telescoping section remains outside of the introducer sheath. The telescoping section allows the imaging core to be advanced and retracted within 25 cm of linear movement.

The imaging core is composed of a hi-torque flexible, rotating drive cable with a radially looking 15 MHz ultrasonic transducer at the distal tip. An electro-mechanical connector interface at the proximal end makes the connection to the MotorDrive Unit (MDU) / Instrument. The MDU-Catheter interface consists of an integrated mechanical drive hub and electrical connection.

A flush port with a one-way valve is used to displace air near the transducer. The catheter must be flushed with heparinized saline prior to use, as this provides the acoustic coupling media required for ultrasonic imaging. The one-way valve helps retain saline in the catheter during use.

The catheter sheath is attached to the telescope shaft via a male/female luer connection. The catheter is for use with the BSS ClearView Ultra™ and Galaxy™ IVUS Imaging Systems.

Intended Use/Indications:

The Atlantis™ PV Imaging Catheter is intended for ultrasound examination of peripheral pathology only. Intravascular ultrasound imaging is indicated in patients who are candidates for transluminal interventional procedures.

Device Technology Characteristics an Comparison to Predicate Device:

The Atlantis™ PV Imaging Catheter utilizes the same basic catheter design as the predicate devices, the BSS Sonicath Ultra™ 6 and Sonicath Ultra™ 3.2 Imaging Catheters. These devices have the same intended use, use the same operating principal, and incorporate that same basic catheter design. In addition, the BSS Sonicath Ultra™ 6 has the same shelf life, and is packaged

using the same materials and processes as the predicate device. The modifications to Atlantis™ PV Imaging Catheter include a telescoping section, a dual lumen sheath, a radiopaque catheter tip, a proximal flush port with a one-way valve and vent hole, and gold plated distal housing. The Atlantis™ PV Imaging Catheter will be sterilized by E-Beam irradiation, rather than by gamma irradiation, as are the BSS Sonicath Ultra™ 6 and Sonicath Ultra™3.2 Catheters.

Non-clinical Test Results:

Bench, acoustic output, animal and biological safety testing demonstrate that the Atlantis™ PV Imaging Catheter is safe and effective for its intended use.

Bench Testing:

Bench testing was performed to evaluate the physical integrity and functionality of the catheter. This testing included dimensional testing, sheath bond tensile testing, and a variety of functional performance testing of the sheath and telescoping assembly, the imaging core assembly, and of the final sterile device.

Acoustic Output Testing:

The Atlantis PV imaging catheter was tested for acoustic output as described in the FDA Guidance, *Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers (Sept. 30, 1997)*. Acoustic output test results for the Atlantis™ PV imaging catheter are below the FDA Track 1 limits.

Animal:

Animal testing was performed to assess the *in-vivo* functional and imaging characteristics of the Atlantis™ PV imaging catheter. The performance of the Atlantis™ PV imaging Catheter was consistent with the intended clinical use of the device.

Biological Safety Testing:

The Atlantis™ PV Imaging Catheter was subjected to a series of biocompatibility tests per ISO 10993, bioburden, endotoxin and sterility assurance testing.

Conclusion:

The Atlantis™ PV Imaging Catheter utilizes design features and has the same intended use as the predicate devices, the BSS Sonicath Ultra™ 6 and

Sonicath Ultra™ 3.2 imaging catheters. The tests support a determination of substantial equivalence of the modified device, the Atlantis™ PV imaging Catheter to the predicate devices.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Boston Scientific Scimed
c/o Ms. Irene Jaworski
Manager, Regulatory Affairs
IVUS Technology Center
47900 Bayside Parkway
Fremont, CA 94538

Re: K022860
Trade Name: Atlantis™ PV Imaging Catheter
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic Ultrasonic Transducer
Regulatory Class: Class II (two)
Product Code: ITX
Dated: October 23, 2002
Received: October 24, 2002

Dear Ms. Jaworski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

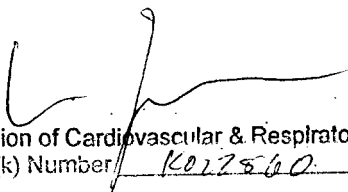
510(k) Number: _____

Device Name: **Atlantis™ PV Imaging Catheter**

Indications for Use: The Atlantis™ PV Imaging Catheter is intended for ultrasound examination of peripheral pathology only. Intravascular ultrasound imaging is indicated in patients who are candidates for transluminal interventional procedures.

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IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


Division of Cardiovascular & Respiratory Devices
510(k) Number K012560

Prescription Use ☒
Per 21 CFR 801.109

OR

Over the counter Use _____